REMARKS

I. Status of the Application

Claims 186, 189-194, 197, and 199-203 are pending following amendments to the claims made herein.

II. Interview Summary

On December 9, 2008, Applicants' representative, Tanya A. Arenson and Examiner Fubara conducted a telephone interview. The outstanding rejections under 35 U.S.C. 103 were discussed. The Applicants' representative pointed out that the presently claimed invention specifically excluded elements of the prior art references and that the prior art references did not teach or suggest the presently claimed invention.

III. The Claims Are Supported by the Specification

The Examiner rejects claims 202 and 203 under 35 U.S.C. § 112, first paragraph as allegedly failing to comply with the written description requirement. (Office Action at page 2). Applicants respectfully disagree.

Applicants respectfully submit that the Specification provides support for the claims (e.g., for the amount of each component claimed). Specifically, support for 3-15% ethanol can be found on page 21, lines 7-13 and 23; support for 3-15% surfactant can be found on page 21, lines 29-30, support for cetylpyridinium chloride can be found on page 37, lines 26-27; and page 38, lines 24-27, respectively, and support for EDTA can be found on page 26, lines 19-21. Applicants note that the specification specifically contemplates the addition of EDTA to any composition (See e.g., page 22, line 31 to page 23, line 20).

Accordingly, no new matter has been added. Applicants respectfully submit that the Claims are supported by the Specification and request that the Examiner withdraw the rejection under 35 U.S.C. § 112, first paragraph.

IV. The Claims are Not Obvious

The Examiner rejected Claims 186-194, 197 and 199-203 under 35 U.S.C. §103(a) as allegedly being unpatentable over Libin (U.S. Pat. No. 5,855,872) in view of Stroud et al. (U.S. Pat.

No. 6,231,837); Claims 186-188, 191, 193, 194 and 197-200, 202 and 203 as allegedly being unpatentable over Asculai et al. (US Pat. No. 4,020,183) in view of Keith et al. (US Pat No. 4,350,707); and Claims 202 and 203 as allegedly being obvious in light of Libin in view of Thomsen et al (US 6.342,537; hereinafter Thomsen I) or Thomsen et al. (US 5,981,605; hereinafter Thomsen II) in view of Asculai. Applicants respectfully disagree.

In rejecting claims under 35 U.S.C. § 103, the Examiner bears the initial burden of presenting a prima facie case of obviousness.[1] A prima facie case of obviousness is established when the teachings from the prior art itself would appear to have suggested the claimed subject matter to a person of ordinary skill in the art.[2] An obviousness analysis requires that the prior art both suggest the claimed subject matter and reveal a reasonable expectation of success to one reasonably skilled in the art.[3]

The test for *prima facie* obviousness is consistent with legal principles enunciated in *KSR Int'l Co. v. Teleflex Inc.,* 127 S. Ct. 1727 (2007). The Federal Circuit summarized the Supreme Court's holding in *KSR* that "While the *KSR* Court rejected a rigid application of the teaching, suggestion, or motivation ("TSM") test, the Court acknowledged the importance of identifying 'a ***reason*** that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does' in an obviousness determination." *Takeda Chem. Indus., Ltd. v. Alphapharma Pty., Ltd., 06-1329, slip op. (Fed. Cir. June 28, 2007)*, at 13-14 (quoting *KSR,* 127 S. Ct. at 1731) (emphasis added). Although the TSM test should not be applied in a rigid manner, it can provide helpful insight to an obviousness inquiry. *KSR,* 127 S. Ct. at 1731. The *KSR* Court upheld the secondary considerations of non-obviounsess, noting that there is "no necessary inconsistency between the idea underlying the TSM test and the *Graham* analysis." *Id.* Additionally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. See M.P.E.P. 2143.

Applicants respectfully submit that the cited references, individually or combined, do not teach or suggest each element of the claimed invention. Moreover, Applicants respectfully submit that the limitations of the amended claims exclude the compositions of the cited references. Applicants further submit that the references do not provide a motivation to combine the references with an expectation of success.

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[1] See In re Rijckaert, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993).
[2] In re Bell, 991 F.2d 781, 783, 26 USPQ2d 1529, 1531 (Fed. Cir. 1993).
[3] In re Vaeck, 947 F.2d 488, 493, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991).

A) The Cited References Do Not Teach or Suggest All Limitations of the Claims

Applicants respectfully submit that the cited references, individually or in combination, do not teach or suggest a method of topically treating a human having a *Herpes simplex I* virus infection, comprising exposing a surface of skin or mucosal cells and tissue of a human to a nanoemulsion composition, or a dilution thereof, the nanoemulsion consisting essentially of 1) a discontinuous oil phase; 2) an aqueous phase; 3) 3-15% by volume ethanol; and 4) 3-15% by volume surfactant; and 5) 0.5-2% or 1-10% by volume halogen-containing compound (e.g., as recited in Claim 186). Similarly, the cited references, individually or in combination, do not teach or suggest a method of topically treating a human having a *Herpes simplex I* virus infection, comprising exposing a surface of skin or mucosal cells and tissue of a human to a nanoemulsion composition, or a dilution thereof, said nanoemulsion composition consisting essentially of: 1) 50-80% by volume oil; 2) distilled water; 3) 3-15% by volume ethanol; 4) 3-15% by volume surfactant; and 5) 0.5-2% or 1-10% by volume cetylpyridinium chloride (e.g., as recited in Claim 200); nor a method of topically treating a human having a *Herpes simplex I* virus infection, comprising exposing a surface of skin or mucosal cells and tissue of a human to a nanoemulsion composition, or a dilution thereof, said nanoemulsion composition consisting of: 1) 3-15% by volume surfactant; 2) 3-15% by volume ethanol; 3) 50-80% by volume oil; 4) cetylpyridinium chloride; 5) distilled water; and 6) ethylenediaminetetraacetic acid (e.g., as recited in Claim 202).

Thus, the cited references, individually or in combination, fail to teach or suggest all the claim limitations.

Applicants further submit that the compositions and methods of using the same disclosed by the cited references are excluded by the limitations of the amended claims. For example, the presently claimed invention requires that the compositions **consist essentially of** the recited components. The compositions of Libin specifically require elements (e.g., an antimicrobial agent such as Triclosan) that are specifically excluded by the presently claimed invention. In particular, Libin states:

> "dispersed in the emulsion is an antimicrobial composite created by two distinct antimicrobial agents, one being non-cationic and the other cationic. When combined, the agents act synergistically to promote their delivery and retention on the HSV infected tissues.

> Non-cationic antibacterial agents, which are particularly desirable in terms of effectiveness and safety are halogenated di-phenyl ethers, preferably Ticlosan." Libin, column 3, 2nd-3rd paragraph.

Thus, Libin is not suitable as a reference because it requires a component excluded by the presently claimed invention. Likewise, Stround, is directed to compositions for sunless tanning, requires elements (e.g., skin darkening agents) that are specifically excluded by the present invention. Thus, Libin, alone or in combination with Stroud, does not teach a composition that consists essentially of the components of the presently claimed compositions. Likewise, neither Thomsen or Mulder provide such a composition. Thomsen specifically excludes surfactants from the recited compositions (See e.g., column 9, last full paragraph).

Likewise, neither Keith nor Asculai teach or suggest a composition consisting essentially of the recited components. Indeed, the compositions of Keith specifically require butylated hydroxytoluene, which is excluded by the compositions of the present invention. In addition, neither Asculai nor Keith, alone or in combination teach the claim element of cetylpyridinium chloride. Indeed, Asculai only mentions cetylpyridinium chloride in the background discussion as the work of others and does not provide or suggest the use of any compositions comprising cetylpyridinium chloride. Thus, Asculai, alone or in combination with Keith, does not teach a composition that consists essentially of the components of the presently claimed compositions.

Nonetheless, without acquiescing to the Examiner's arguments and while reserving the right to prosecute the original or similar claims in the future, Applicants have amended the claims in order to further the prosecution of the application and their business interests. In particular, the Applicants have amended Claim 186 to include the element of the halogen-containing compound being cetylpyridinium chloride. Claims 186, 200 and 202 have been amended to include the step of contacting the skin or tissue with the nanoemulsion such that said nanoemulsion kills said *Herpes simplex I* virus. As described above, none of the cited art, alone or in combination, teach these claim elements. The Applicants have further added new claims 204-206 which state that the nanoemulsion has a mean particle size of approximately 0.2 to 0.8 microns. Support for the new claims can be found, for example, on Pg. 13, line 12-21 and in paragraph 102. None of the cited references, alone or in combination teach the claim element of a nanoemulsion with a mean particle size of 0.2 to 0.8 microns having the claimed ingredients or properites.

B) The cited references do not provide a motivation to combine the references

The Supreme Court in *Graham* established specific steps for a non-obvious analysis: (1) determine the scope and content of the prior art; (2) evaluate the differences between the prior art and the claims at issue; and (3) determine the level of ordinary skill in the art.[4] "Against this background, the obviousness or non-obviousness of the subject matter is determined."[5] These *Graham* steps provide a subjective analysis of whether an invention was obvious **at the time it was made**.

Thus, the non-obvious standard of § 103(a) requires the Examiner to make a historical judgment: whether the invention would have been obvious **at the time the invention was made** in the past. To reach a proper non-obvious conclusion, the Examiner must not only step backward in time to a moment when the invention was unknown, but also avoid letting knowledge that the invention was achieved affect his or her decision about whether it was obvious at the time it was achieved.[6] The courts have recognized that meeting this standard "requires the oft-difficult but critical step of casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field."[7]

In an effort to preclude such an improper result, the Federal Circuit requires that the non-obvious analysis be conducted viewing the invention as a whole.[8] Using "'hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention'"[9]or conducting a "reference-by-reference, limitation-by-limitation analysis" fails to demonstrate how the invention is obvious in light of prior art.[10] Similarly, the Examiner

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[4] See *Graham*, 383 U.S. at 17.
[5] Id.
[6] *Graham v. John Deere Co.*, 383 U.S. 1, 36 (1966)
[7] *In re Dembiczak*, 175 F.3d at 999 (emphasis added); see also *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1553 (Fed. Cir. 1983) ("It is difficult but necessary that the decisionmaker forget what he or she has been taught at trial about the claimed invention and cast the mind back to the time the invention was made (often as here many years), to occupy the mind of one skilled in the art who is presented only with the references, and who is normally guided by the then-accepted wisdom in the art.").
[8] See *Ruiz v. A.B. Chance Co.*, 357 F.3d 1270, 1275 (Fed. Cir. 2004).

[9] *Ecolochem, Inc. v. S. Cal. Edison Co.*, 227 F.3d 1361, 1371 (Fed. Cir. 2000) (quoting *In re Fine*, 837 F.2d 1071, 1075 (1988)).
[10] *Id.*, at 1374

may not use the invention as a blueprint for linking together pieces of prior art in order to find the invention obvious.[11] The Federal Circuit has referred to using the invention as a "blueprint for piecing together the prior art . . . [as] the essence of hindsight."[12]

Applicants contend that the Examiner has improperly utilized hindsight reconstruction of the claimed invention in an effort to support the allegation that the claimed invention is prima facie obvious. Applicants contend that, at the time the invention was made, there existed no explicit or implicit teaching or suggestion or motivation to modify or combine elements present in the art to generate the claimed invention. That is, prior to the disclosure of the present invention, there existed no teaching, from anywhere, regarding the claimed methods, which require compositions that consist essentially of specific recited components.

Applicants contend that if the Examiner's allegation were true (i.e., that it would have been obvious to generate a nanoemulsion composition of the claimed invention that topically treated a *Herpes simplex I* infection using the teachings of the cited references), then at least the cited references would have suggested the same. For example, if it were obvious to use the surfactant, ethanol and interaction enhancer (e.g., EDTA) of Stroud in the antiviral compositions of Libin, then one would expect Libin or Stroud to have recognized and recited such modifications. No such suggestion is found. Indeed, Stroud is in a totally unrelated area of art (self-tanning compositions). One working in the field of virology would not have considered using compositions for self-tanning in designing topical antiviral agents. Further, Libin does not identify any defects in the recited compositions that would lead one of skill in the art to seek modifications. Indeed, Libin very clearly states that the compositions are suitable for use as described.

Likewise, neither Asculai nor Keith teach or suggest modifying the disclosed compositions. Neither Asculai nor Keith provides any teaching that the disclosed compositions are lacking in functionality or would otherwise benefit from the combination.

Furthermore, neither Thomsen I nor Thomsen II provide any teaching or suggestion that the disclosed compositions be modified or combined with Libin and Asculai.

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[11] *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1143 (Fed. Cir. 1985).
[12] *In re Dembiczak*, 175 F.3d 994, 999 (Fed. Cir. 1999)

Applicants respectfully submit that the cited references fail to provide such evidence or teachings because the Examiner's allegations are erroneous. Applicants contend that the hindsight reconstruction of the claimed invention is factually and legally unsupportable.

Instead, the rejection has inappropriately hand-picked elements from multiple (i.e., two to three), non-related disclosures in an effort to recreate the claimed invention. Applicants contend that the factual support found in the Specifications of the cited references indicates that those of ordinary skill in the art at the time of the invention failed to recognize an explicit or implicit teaching from anywhere to make the claimed invention. Instead, Applicants contend that the Examiner is **using the invention as a blueprint for linking together pieces of the cited references** in order to find the invention obvious. Applicants contend that this type of analysis is in error. Moreover, as described above, linking the teachings of the cited references fails to teach, disclose or suggest each of the limitations of the claimed invention.

C) The cited references provide no expectation for success for carrying out the claimed invention

Applicants respectfully submit that the Examiner has mischaracterized the references. The cited references do not teach or suggest each element of the claimed invention. The cited references individually or collectively further do not enable one of ordinary skill in the art to make and use the claimed invention. Moreover, because the cited references fail to teach one of ordinary skill in the art how to make and use the claimed invention, prior to the disclosure of the present invention, one of skill in the art would have possessed no reasonable expectation of success for generating a pharmaceutical composition of the claimed invention.

As described above, the art cited by the Examiner fails to teach the compositions of the present invention and fails to provide a motivation to combine the teachings to arrive at the presently claimed invention. In addition, even if the combination is improperly made, the cited art provides no expectation that the compositions would have the desired property of treating a *Herpes simplex I* infection as required by the methods of the presently claimed invention. For example, as described above, Libin does not suggest any modifications to the disclosed compositions and methods. Libin's antiviral active agent (Triclosan) would have to be excluded under the claims. As such, there is no reason to think Libin's formulation, even as modified under the rejection would be anti-viral. Stroud does not relate to treatment of *Herpes simplex I*

infections and thus does not provide any expectation of success. Neither Keith, Thomsen I, Thomsen II nor Asculai provide any teaching that even if the references were improperly combined, the resulting compositions would have the recited properties of treating *Herpes simplex I* infections.

The present invention is not simply directed to a nanoemulsion composition consisting essentially of the recited components but is instead directed to a method of topically treating a human having a *Herpes simplex I* virus infection. There is no indication in any of the cited references of a method of treating *Herpes simplex I* using a composition consisting essentially of the disclosed compositions.

In addition, in order to generate the compositions utilized in the presently claimed methods, one would need to remove required components from the compositions cited in the references (see section A above). Thus, one would not expect the compositions to retain their recited properties (e.g., anti viral properties).

Thus, Applicants respectfully request that the rejections made under 35 U.S.C. § 103 be reconsidered and withdrawn on the grounds that the references, individually or in combination, do not provide a motivation to combine the references with a reasonable expectation of success, and even if improperly combined, the references do not teach or suggest each and every element of the claimed invention.

CONCLUSION

For the reasons set forth above, it is respectfully submitted that Applicants have addressed all grounds for rejection and Applicants' claims should be passed to allowance. Reconsideration of the application is respectfully requested. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, Applicants encourage the Examiner to call the undersigned collect at (608) 218-6900.

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